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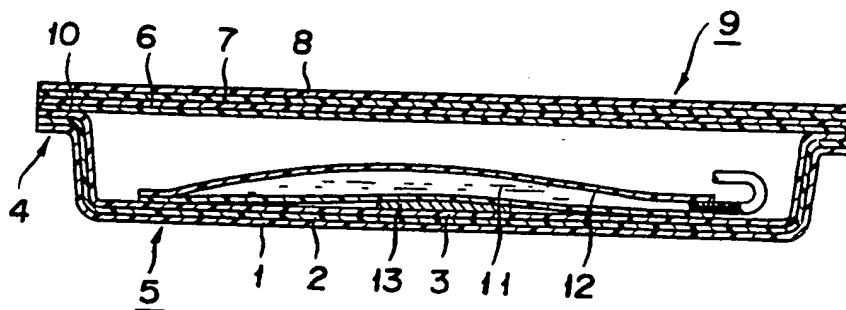
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(54) Package for storage of medical
 container

(57) A package for the storage of a
 plastics medical container holding a
 medicinal fluid therein, which package
 comprises a tray part 5 formed by
 laminating and molding an outer
 polyolefin layer 11, an intermediate
 layer 2 capable of resisting passage of
 gases and steam and an inner

polyolefin layer 3 in the shape of a tray
 provided round the opening thereof
 with a flange portion 4, a lid member
 9 formed by laminating an inner
 polyamide layer 6, an intermediate
 layer 7 capable of resisting passage of
 gases and steam and an outer layer 8
 of a resin of sufficient thermal
 resistance to withstand the conditions
 of heat sealing, and a hot melt
 adhesive layer 10 formed of materials
 of dissimilar melting points including
 at least one material the same as
 polyolefin in one layer of the tray and
 adapted to be inserted between the
 tray flange portion and the
 corresponding portion of the lid
 member to form a peelable heat seal
 therebetween.

FIG.2



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FIG. 1

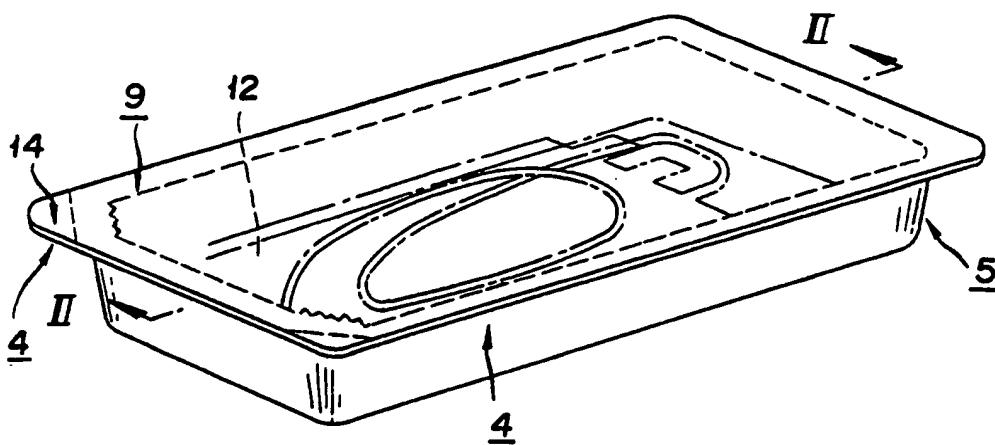
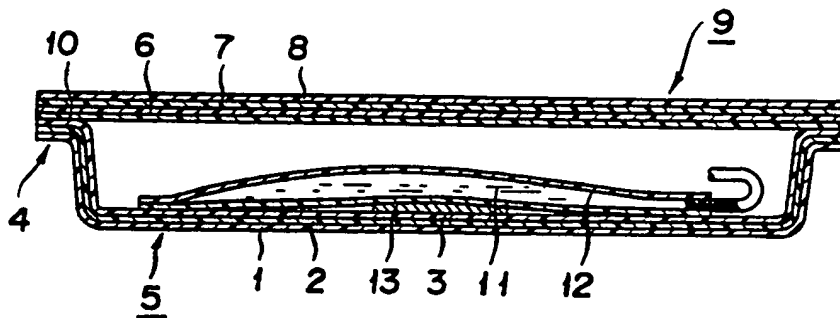


FIG. 2



SPECIFICATION

Package for storage of medical container

This invention relates to a package for storing a plastics medical container. More particularly, this invention relates to a package for the storage of a plastics medical container such as a blood bag or a
5 transfusion solution bag which contains therein a medicinal fluid. 5

Plastics medical containers such as blood bag and transfusion bags contain therein anticoagulants such as ACD solution and CPD solution which serve to prevent the blood from being coagulated during collection or transfusion of blood. The medical containers containing such chemical solutions are stored in tightly closed packages of synthetic resin designed exclusively for the purpose of storage.
10 Since the medical containers are made of plastics materials and therefore are pervious to gases, there is a possibility that oxygen gas, for example, will penetrate through these containers and pass into the solutions contained therein to cause oxidative degradation of the chemical solutions. The wetting components, particularly the moisture, present in the chemical solutions penetrate through the walls of the containers and add to the humidity within the packages. If aerobic microorganisms survive by some
15 reason or other within the chemical solutions, there is the possibility that the microorganisms, which collect on the surface of the containers between the time these containers are manufactured and the time they are put to use, will proliferate because of the heightened humidity. 15

It has been recently proposed to put deoxidizer in the packages to effect quick reduction of concentration of oxygen within the tightly closed packages and prevent the contents of the containers from oxidising. As a tightly closed package suited to the prevention of its contents from oxidising, there
20 has been proposed a bag-shaped package which is obtained by vacuum depositing aluminum on the opposed surfaces of two superposed polyester type resin sheets and heat sealing the corresponding peripheries of the two sheets by way of a hot melt type adhesive agent (Japanese Published Unexamined Patent No. SHO 53(1978)—113693). Since the bag-shaped package is deficient in shape-
25 retaining property, the inner volume of the package decreases and its walls collapse as the oxygen therein is gradually absorbed by the deoxidizer. When the contents of the package and the walls of the package adhere fast to the surfaces of the deoxidizer, the absorption of oxygen by the deoxidizer fails to proceed at the expected rate and the concentration of oxygen in the package fails to fall to the prescribed level (less than 0.1%/50 hrs.), frequently with the result that microorganisms which by
30 chance have found their way into the containers in the course of fabrication will enjoy growth in the presence of oxygen. Since the bag-shaped package has an inferior shape-retaining property, it tends to be inconvenient for storage. When such bag-shaped packages are piled up during storage or in transit, they can collapse with adverse effects upon their contents. If the prior package is molded three-
35 dimensionally, the conditions involved in the molding deform and crack the conventional gas and steam barrier layers formed of aluminum and the package thus is non effective as a gas barrier. 35

The present invention provides a package for the storage of a plastics medical container holding a medicinal fluid therein, which package has (a) tray provided round the opening thereof with a flange portion, and formed by a laminate comprising an outer polyolefin layer, an intermediate layer to act as a barrier to passage of gases and steam, and an inner polyolefin layer, (b) a lid member comprising a
40 laminate of an inner polyamide layer, an intermediate layer to act as a barrier to passage of gases and steam, and an outer resin layer of sufficient thermal resistance to withstand the conditions of heat sealing, and (c) a hot melt adhesive layer for forming a peelable heat seal between the said inner layers of the tray and lid member and formed of materials of dissimilar melting points including at least one material substantially the same as a polyolefin of a tray layer. 40

The invention also provides such a package when assembled and sealed, i.e. when containing the
45 container of medical fluid and with lid member and tray flange peelably heat sealed via the hot melt adhesive layer. 45

The polyolefin layers of the tray may be of polypropylene and the hot melt adhesive layer of a blend of polyethylene with polypropylene; the weight ratio of polyethylene to polypropylene in this hot
50 melt adhesive layer is suitably from 20:80 to 50:50. The intermediate layer of the lid member is suitably of polyvinylidene chloride or ethylene-vinyl alcohol copolymer. The intermediate layer of the tray is suitably of ethylene-vinyl alcohol copolymer. The thermally resistant outer layer of the lid member is suitably of polyester, polyamide or polypropylene. The tray part may be transparent. 50

The invention is illustrated, by way of example only, in the accompanying drawings, in which:—
55 FIG. 1 is a perspective view of an assembled and sealed package according to the present invention, and 55

FIG. 2 is a cross section taken along the line II—II of FIG. 1.

The illustrated package is produced by preparing a tray part 5 provided round the opening thereof with a flange portion 4 by molding a laminated sheet comprising a polyolefin layer (outer layer) 1, a
60 layer 2 capable of resisting passage of gases and steam (intermediate layer), and a polyolefin layer (inner layer) 3; separately preparing a lid member 9 by laminating a polyamide layer (inner layer) 6, a layer 7 capable of resisting passage of gases and steam (intermediate layer), and a layer 8 of sufficient thermal resistance to withstand the conditions of heat sealing (outer layer); preparing a hot melt
adhesive layer 10 comprising a plurality of materials having dissimilar melting points and including 60

over the entire surface of the lid member. Of course, any deoxidizer may be placed in the tray 5 before, simultaneously with or after the medical container 12.

The present invention is illustrated more specifically below in working Examples 1 to 10:

As illustrated in FIGS. 1 and 2, in a tray part 5 formed of a laminated sheet comprising an outer layer 1 of polypropylene (having a molecular weight of 100,000 to 500,000) 500 μ m in thickness, an intermediate layer 2 of ethylene-vinyl alcohol copolymer (having a molecular weight of 10,000 to 50,000) 5 μ m in thickness, and an inner layer 3 of polypropylene (having a molecular weight of 100,000 to 500,000) 500 μ m in thickness, was set a pack of deoxidizer in a bag-like container having as one wall a gas pervious sheet of paper. Further a blood bag 12 made of polyvinyl chloride and containing therein an anticoagulant was set in position in the tray part 5. Then a lid member 9, obtained by laminating a layer 6 composed of nylon 10 μ m in thickness and a high barrier layer 10 μ m in thickness, an intermediate layer 7 composed of two layers each of a film of biaxially drawn polypropylene (having a molecular weight of 100,000 to 500,000) 20 μ m in thickness superposed by a layer of polyvinylidene chloride (having a molecular weight of 10,000 to 15,000) 10 μ m in thickness, and an outer layer 8 of polyethylene terephthalate (having a molecular weight of 100,000 to 500,000). 15 was heat sealed by high frequency to the flange portion 4 of the tray part 5 by way of a hot melt adhesive layer 10 of a blend of polyethylene (having a molecular weight of 50,000 to 100,000) and polypropylene (having a molecular weight of 100,000 to 500,000) in a weight ratio of 70:30 and superposed in advance on the flange portion 4 of the tray part 5. The packages thus produced were 20 tested for concentration of oxygen contained therein by the use of a zirconia type analyzer (made by Toray Ltd). The results were as shown in Table 1. When the procedure described above was repeated by using ethylene-vinyl alcohol copolymer as the material for the layer of the lid member capable of resisting passage of gases and steam, there were obtained similar results.

Table 1

Example No.	Oxygen concentration (% by volume)				
	After 24 hrs	After 33 hrs	After 48 hrs	After 53 hrs	After 57 hrs
1	110	6.5	0.153	0.075	0.0038
2	—	6.8	0.264	0.042	—
3	—	7.3	0.065	0.038	—
4	—	—	0.072	0.032	—
5	—	—	0.283	0.041	—
6	—	—	0.156	0.011	—
7	—	—	0.090	0.024	—
8	—	—	0.017	0.012	—
9	—	—	0.013	0.023	—
10	—	—	0.061	0.017	—

As described above, the package of this invention for the storage of a medical container is obtained by preparing a tray part provided round the opening thereof with a flange portion by molding a laminated sheet comprising a polyolefin layer, a layer capable of resisting passage of gases and steam, and a polyolefin layer, separately preparing a lid member formed by laminating a polyamide layer, a layer capable of resisting passage of gases and steam and a layer of sufficient thermal resistance to withstand the conditions of heat sealing, also preparing a hotmelt adhesive layer, and tightly heat sealing the flange portion 4 of the tray part and the corresponding portion of the lid member via the adhesive layer to form a peelable seal. Because of the inner and outer polyolefin layers, the tray part can enjoy high shape-retaining property and transparency. With use of ethylene-vinyl alcohol copolymer as the layer capable of resisting passage of gases and steam, the tray part combines transparency and a high ability to resist passage of gases (including oxygen) and steam. The lid member has a high ability to resist passage of gases and steam when polyvinylidene chloride or ethylene-vinyl alcohol copolymer is used as or in the intermediate layer. When polyester, polyamide or polypropylene is selected as the resin for the outer layer required to withstand the conditions of heat sealing, the lid member has ample

shape-retaining property in spite of the conditions of heat sealing. When all these layers are transparent, the condition of the medical container inside the package can be readily inspected without opening the package. When polypropylene is selected for the polyolefin layers in the tray part and a blend of polyethylene with polypropylene is selected for the hotmelt adhesive layer, with the weight ratio of polyethylene to polypropylene falling in the range of 20:80 to 50:50, the package has ample adhesive strength and excels in peel openability.

- Even when the package of this invention contains a medical container such as a blood bag or transfusion bag made of a material such as polyvinyl chloride which is highly pervious to steam and containing an anticoagulant, a fluid for transfusion or other similar medicinal fluid, it can prevent passage of gases and, therefore prevent oxygen in the ambient air from penetrating into the therapeutic container. Particularly when deoxidizer is contained simultaneously with the medical container in the package, the interior of the package can be retained in a substantially oxygen-free condition with the medicinal fluid in the medical container free from oxidative deterioration. If aerobic microorganisms by chance find their way into the medical container, they are not allowed to attain growth in the absence of oxygen. The package, accordingly, can keep its interior in a substantially sterilized condition. Further the package can resist leakage of steam in both directions; steam which diffuses out of the medical container is only allowed to saturate the interior of the package and is not allowed to escape from the package. Thus, the medicinal fluid in the medical container is not lost while the container is stored in the package. By having at least the tray part of the package formed of transparent layers, the medical container stored inside the package can be inspected without opening the package.
- The invention thus provides a package for a container of medicinal fluid, the package comprising (a) a tray having a flange around its opening and formed of a laminate comprising polyolefin layers with a gas and steam barrier layer therebetween, (b) a lid formed of a laminate of polyamide and thermally resistant resin layers with a gas and steam barrier layer therebetween, and (c) a hot melt adhesive for forming a peelable heat seal between the tray flange and polyamide lid layer.

CLAIMS

1. A package for the storage of a plastics medical container holding a medicinal fluid therein, which package has (a) tray provided round the opening thereof with a flange portion, and formed by a laminate comprising an outer polyolefin layer, an intermediate layer to act as a barrier to passage of gases and steam, and an inner polyolefin layer, (b) a lid member comprising a laminate of an inner polyamide layer, an intermediate layer to act as a barrier to passage of gases and steam, and an outer resin layer of sufficient thermal resistance to withstand the conditions of heat sealing, and (c) a hot melt adhesive layer for forming a peelable heat seal between the said inner layers of the tray and lid member and formed of materials of dissimilar melting points including at least one material substantially the same as a polyolefin of a tray layer.
2. A package according to claim 1 wherein the polyolefin layer of the tray comprises polypropylene and the hot melt adhesive layer comprises a blend of polyethylene with polypropylene.
3. A package according to claim 2 wherein the weight ratio of polyethylene to polypropylene in the hot melt adhesive layer is in the range of 20:80 to 50:50.
4. A package according to any preceding claim wherein the intermediate layer of the lid member comprises a polyvinylidene chloride or ethylene-vinyl alcohol copolymer.
5. A package according to any of claims 1 to 3 wherein the intermediate layer of the lid member comprises superposed layers of polyvinylidene chloride and polyolefin.
6. A package according to any preceding claim wherein the intermediate layer of the tray comprises ethylene-vinyl alcohol copolymer or polyvinylidene chloride.
7. A package according to any preceding claim wherein the thermally resistant layer is selected from polyesters, polyamides and polypropylene.
8. A package according to any preceding claim wherein at least the tray is transparent.
9. A package according to any preceding claim containing a container of medicinal fluid and having the lid member and tray flange peelably sealed via the hot melt adhesive layer.
10. A package for a container of medicinal fluid, the package being substantially as hereinbefore described with reference to the accompanying drawings.
11. A package for a container of medicinal fluid, the package being substantially as described in any Example herein.
12. A package for a container of medicinal fluid, the package comprising (a) a tray having a flange around its opening and formed of a laminate comprising polyolefin layers with a gas and steam barrier layer therebetween, (b) a lid formed of a laminate of polyamide and thermally resistant resin layers with a gas and steam barrier layer therebetween, and (c) a hot melt adhesive for forming a peelable heat seal between the tray flange and polyamide lid layer.